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14. ABSTRACT
This 3-arm randomized controlled trial evaluates the efficacy of a CD-ROM based multimedia prostate cancer education system (PIES). PIES is an educational software that provides patients with information about prostate cancer and its treatment through an intuitive interface, using video, animation, text, and voice-over text. All text is tailored to a person's information seeking preference. Participants (N = 86) are patients diagnosed with localized prostate cancer who will be randomized into three experimental conditions: a) Standard care, involving the provision of standard NCI print material about prostate cancer, Group 1; b) PIES software without tailoring component, Group 2; c) and PIES software with tailoring component, Group 3. Assessments will be taken prior to exploring the software/brochures, immediately after completing the software/brochure, and 6-weeks post baseline. The study design allows for the evaluation of the efficacy of the multimedia intervention against traditional care; the influence of tailoring versus not tailoring information within a multimedia context; and for an evaluation of the moderating effect of monitoring on the efficacy of the groups.

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Table of Contents

Abstract……..4

Introduction…….....5

Body……6

Key Research Accomplishments……...8

Conclusions……..9

Reportable Outcomes……9

References……9

Appendices……10

Supporting Data……10

W81 XWH-04-1-0179: Evaluating an interactive, multimedia education and decision program for early-stage prostate cancer patients in a randomized controlled trial.
PI: Michael A. Diefenbach, Ph.D.

Abstract

This 3-arm randomized controlled trial evaluates the efficacy of a CD-ROM based multimedia prostate cancer education system (PIES) developed by our research group. PIES is an educational software that provides patients with information about prostate cancer and its treatment through an intuitive interface, using video, animation, text, and voice-over text. All text is tailored to a person's information seeking preference (i.e., high versus low monitors). Participants (N = 86) are patients diagnosed with localized prostate cancer who will be randomized into three experimental conditions: a) Standard care, involving the provision of standard NCI print material about prostate cancer (Group 1); b) PIES software without tailoring component (Group 2); c) and PIES software with tailoring component (Group 3). Assessments will be taken prior to exploring the software/brochures, immediately after completing the software/brochure, and 6-weeks post baseline. The study design allows for three main comparisons: it evaluates the efficacy of the multimedia intervention against traditional print materials or standard care; it evaluates the influence of tailoring versus not tailoring information within a multimedia context; and, it allows for an evaluation of the moderating effect of monitoring on the efficacy of the intervention groups.

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PI: Michael A. Diefenbach, Ph.D.

Introduction: Despite advances in treatment, uniform treatment recommendations for localized prostate cancer have yet to emerge. Consequently, men with this diagnosis are faced with a complex set of disease information and treatment challenges as they select a treatment option (Diefenbach, et al., 2002). To educate patients about prostate cancer and its treatment and to ease their decisional burden, we have developed an innovative CD-ROM based multimedia prostate cancer interactive education system (PIES; http://www.temple.edu/imits/pies.htm). The development of the software has been guided by our cognitive-affective, self-regulation theoretical framework (Diefenbach & Leventhal, 1996; Miller & Diefenbach, 1998). PIES uses the metaphor of a health center. Patients can explore various rooms to interactively obtain treatment and disease information. PIES goes beyond the inclusion of text, video, audio, and animation, by providing a unique intelligent expert system that tailors text information to the patient's information seeking preferences (high vs. low monitoring; Miller, 1996; Miller & Diefenbach, 1998). Research has identified high monitors as information seeking and being more distressed compared to low monitors, who are classified as information distracting and being less distressed.

Evaluation of a prototype of PIES through focus groups confirmed that the current PIES system is accepted among potential users and found to be easy to use. However, little information exists on the efficacy of multimedia applications with prostate cancer patients, in an applied clinical setting. Further, no information exists on the efficacy of tailoring information within a multimedia context. To address these issues we are proposing to conduct a 3-arm randomized controlled trial, comparing the provision of NCI informational brochures on prostate cancer (i.e., standard care; Group 1) with two versions of PIES. Patients randomized into Group 2 will explore a version of PIES without the tailoring component, whereas patients in Group 3 will explore PIES with a tailoring component and the inclusion of emotionally reassuring messages. Thus, the specific aims are:

Specific Aim 1a: To evaluate the efficacy of an interactive multimedia educational software system for prostate cancer compared to standard care in a 3-arm randomized controlled trial (RCT).
H1a: Patients assigned to the multimedia software conditions (i.e., Groups 2 and 3) will be more satisfied with the information received and will display better prostate cancer knowledge, which will lead to less decisional conflict, as well as better adjustment through lower levels of intrusion and avoidance and cancer specific negative affect, compared to men randomized into standard care, who receive NCI brochures on prostate cancer (Group 1; Main effect for multimedia condition).

Specific Aim 1b: To evaluate the influence of the tailoring component on prostate cancer knowledge, satisfaction with information received, decisional conflict, and adjustment.
H1b: Tailoring information to patients' monitoring preferences (i.e., Group 3), will result in a higher level of satisfaction with the information received, and increased prostate cancer knowledge, which will lead to less decisional conflict, and better adjustment compared to that of patients assigned to multimedia condition without tailoring (i.e., Group 2; Main effect for tailoring).

Specific Aim 2: To evaluate the moderating role of information seeking preferences on the intervention.

H2: Moderating hypothesis: High monitors will benefit more from the tailoring component, compared to low monitors. The high monitor's tendency to react with higher distress scores (e.g., intrusion scores) when presented with threatening information will make him more receptive to the normalizing and reassuring messages presented in the tailoring component. This will result in better adjustment scores for high monitors randomly assigned to receive vs. not receive PIES with tailoring. In contrast, low monitors should have little to no differences in their adjustment scores as a factor of whether they received tailoring vs. not. (Interaction effect between tailoring and information seeking).

This 3-arm randomized controlled trial evaluates the efficacy of PIES. Participants are patients diagnosed with localized prostate cancer who will be randomized into three experimental conditions: a) Standard care, involving the provision of standard NCI print material about prostate cancer (Group 1); b) PIES software without tailoring component (Group 2); c) and PIES software with tailoring component (Group 3). Assessments will be taken prior to exploring the software/brochures, immediately after completing the software/brochure, and 6-weeks post baseline. The study design allows for three main comparisons: it evaluates the efficacy of the multimedia intervention against traditional print materials or standard care; it evaluates the influence of tailoring versus not tailoring information within a multimedia context; and, it allows for an evaluation of the moderating effect of monitoring on the efficacy of the intervention groups.

Body: To expand and speed up accrual we expanded PIES to another study site, Queens Hospital Center (QHC), an affiliate of Mount Sinai School of Medicine (MSSM). Queens Hospital is served by Mount Sinai faculty and therefore it represents a natural expansion. MSSM IRB approval for this expansion was obtained in June 2005. DOD approval was obtained in June, 2006 and recruitment from Queens Hospital Center began in July, 2006. A total of six patients have been enrolled from Queens for a total of 86 patients from both sites.

Ongoing community outreach and awareness to increase enrollment included:

- Mount Sinai Clinical Trials website.
- Monthly meetings with the head of marketing and outreach for the Barbara and Maurice Deane Prostate Health and Research Center to ensure community awareness of PIES.
- Outreach to Support groups. Dr. Diefenbach (PI) maintained his relationship with local support groups such as the local "Man to Man" chapter and gave period talks to the groups. The most recent talk was on January 14th, 2008.
- The research team attended prostate cancer awareness and fund raiser gatherings to introduce PIES to the wider community.
- Distribution of several hundred informational materials advocating PIES at a free prostate cancer screening sponsored by The Daily News at Mount Sinai Hospital.

Narrative of Results:

Prostate cancer patients diagnosed with localized disease who have not made a treatment decision were randomized into the Control Group (n = 21), Intervention Group with tailoring (n = 38), and Intervention without tailoring (n = 27), resulting into N = 86 patients. Patients were on average 61.8 years old (SD = 8.3; range: 44 - 81); 72.1% were married; 34.9% reported being retired; 8.4% completed grade school, 32.5% completed high school and 59% had a college or post graduate degree. The proportion of minority participants is 43% (27.1% African American; 5.9% Hispanic origin; 8.3% other); 58.8% of patients are Caucasian/Non-Hispanic. The average PSA level was 7.39 ng/ml (SD = 6.90) at diagnosis and the average Gleason score after biopsy was 6.14 (SD = 1.17).

Participants were evaluated at baseline and immediately after viewing PIES or the Brochures (Control Group). Among the participants who viewed the PIES program, 92% reported that PIES provided information that helped them make a treatment decision, 84% reported that PIES provided useful information, 88% reported that they are satisfied with the information that PIES provided. An overwhelming majority (90%) believed that PIES provided information that is clear and easy to understand, 94% reported that PIES provided the information that they needed, and 87% reported that PIES provided answers to all their questions.

There were no differences among the main outcome variables (i.e., decisional conflict, decisional uncertainty and value clarification) between the tailored and the non-tailored PIES group (i.e., all *ps* = ns) and thus the two groups were combined for subsequent analyses and compared against the Control Group. Compared to patients in the control condition, analyses of the data indicate that participants who viewed the PIES program felt significantly more confident in their treatment decision ($p < .033$). Patients in the PIES group also reported that the information presented was more effective in calming their fears ($p < .001$) and also lowered their anxiety about the decision making process significantly ($p < .03$), compared to patients in the control group. In contrast, participants in the control group indicated that the information provided in the brochures was confusing ($p = .05$), and that there was too much information ($p < .02$).

Examining baseline data: Analyses of the baseline dataset focused on the assessment of the main outcome variable "decisional conflict." At baseline, prior to a treatment decision, the average total decisional conflict score was $M_{baseline} = 48.87$ (SD = 15.65; scale range = 20 -100), indicating a moderate decisional conflict. Examining the five baseline decisional conflict sub-scales further showed that men were moderately uncertain that they could make an effective decision (M= 55.39; SD = 19.14) and that they needed assistance in sorting out what was important to them (value clarification M= 42.82; SD= 15.74). Patients felt somewhat informed about prostate cancer (M = 44.55; SD= 16.94), and had moderately well developed decisional

support (M = 49.15 (SD = 20. 86). Examining differences among the three groups (i.e., control, PIES with tailoring, and PIES without tailoring) in all decisional conflict variables at baseline showed no significant differences.

Examining the 6-week data: Results showed a markedly significant decrease in the overall decisional conflict score between the baseline assessment and the 6-week assessment among patients who participated in PIES (M_{6week}= 37.09; $F(1, 28) = 18.75$, $p < .001$, ?= .40). Significant decreases were also noted on the decisional conflict subscales among patients who participated in PIES. Men felt they were better able to make an effective decision ($F(1, 18) = 13.04$, $p < .005$, ?= .42), were more able to clarify their values ($F(1, 27) = 6.10$, $p < .05$, ?= .18), had more developed decisional support ($F(1, 28) = 13.45$, $p < .005$, ?= .34).) and felt more certain about the decision they made ($F(1, 27) = 29.89$, $p < .001$, ?= .53). Examining the time effect on all decisional variables between the baseline and the 6-week assessment among patients in the control condition showed that there was a secular trend for an improvement in overall decisional conflict at 6-weeks (M_{6week}= 41.67; $p < .02$; $F = 10.44$, $p < .05$, ?= .64), however, results showed no significant time effects on any of the five subscales from baseline to the 6-week assessments among the control group.

Moderating effect of Monitoring: With regard to the moderating effect of a monitoring informational style, we found that monitoring did not exert any significant influence on the decisional variables. We also found no significant interaction effects between intervention group and monitoring informational style at baseline and at 6-weeks follow-up assessment.

Summary: These results indicate that PIES is well accepted by patients. It is well organized, easy to use, informative, and presents clear and accurate information. Two-thirds of patients indicated that it is helpful with decision making. Patients who used PIES were significantly more confident about their decision and significantly less anxious about their decision. Decisional conflict was reduced from Baseline to 6 weeks among PIES patients on 5 of the 6 scales including overall decisional conflict. To our knowledge this is the first RCT of a complex multimedia education program for prostate cancer that demonstrated efficacy in reducing decisional conflict, improved value clarification, and increased decisional certainty.

Preliminary results from this research also served as pilot data for a successful program project with the Cancer Information Service (P01-CA057586-09A2; Al Marcus, PI). The goal of this program project is to enhance usual phone service by providing callers who are calling with questions about prostate and breast cancer or about breast cancer adjustment after definite treatment access to one of three topic specific websites. These are currently underdevelopment and the experience with PIES has been very influential for the design of the new website.

Key Research Accomplishments:

- Patients randomized into the PIES group were significantly more confident about their treatment decision and overwhelmingly indicated that the program was easy to use; the information was easy to understand and clearly presented.
- Most importantly, patients indicated that the PIES program helped with their treatment decision making and in making them feel less anxious compared to patients in the control group.
- Based on a decisional conflict scale that ranged from 0-100. At baseline, prior to treatment decision, the average decisional conflict was M=49.09 which is considered moderate to high. Post intervention, which was six weeks after the baseline evaluation; participants that viewed PIES reduced their overall decisional conflict significantly to M=37.09.

- Participants that viewed PIES felt they were better able to make an effective treatment decision, were more informed about their decision, and were better able to clarify their values.

Conclusions: This is the first RCT of a complex multimedia education program demonstrating efficacy in reducing decisional conflict, improving value clarification, and increasing decisional certainty. These results have wide ranging implications for the development of decision aids not only for prostate cancer, but also for other cancers.

Reportable Outcomes:

Diefenbach, M.A. (2005). Multimedia technology for cancer patients. Hospital Pharmacy Europe, November/December: 42-43.

Diefenbach, M.A., Butz, B.P. (2004). The development of an interactive multimedia software program for prostate cancer patients. Journal of Medical Internet Research. 6 (1) e3. http://www.jmir.org/2004/1/e3/

Invited Presentations:

Prostate Cancer, Decision Making, and Quality of Life: The Prostate Interactive Education System. A special seminar at the Institute for Healthcare Studies at the Center on Outcomes, Research and Education (CORE) at Evanston Northwestern University's Feinberg School of Medicine, Evanston, Il, September 27, 2007.

Conference presentations:

Diefenbach, M.A., Butz, B.P. (2005, June). The Design and implementation of intelligent, interactive health education software. Presentation at the NCI conference "Critical Issues in eHealth Research Conference," Bethesda, MD (June 9-10).

Diefenbach, M.A., Butz, B.P. (2004, December). The Prostate Interactive Education System (PIES): A multimedia education software program for prostate cancer patients with tailoring component and decision aid. Presentation at the 2nd Workshop on Prostate Cancer Informatics and the Internet, Toronto, Canada. *Received Best Poster Award*

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Diefenbach, M.A., Dorsey, J., Uzzo, R.G., Hanks, G.E., Greenberg, R.E., Horwitz, E., Newton, F., Engstrom, P.F. (2002). Decision making strategies for patients with localized prostate cancer. *Seminars in Urologic Oncology, 20 (1),* 55-62.

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Miller, S.M. & Diefenbach, M.A. (1998). C-SHIP: A cognitive-social health information processing approach to cancer. In D. Krantz (Ed.), *Perspectives in Behavioral Medicine* (219-244). NJ: Lawrence Erlbaum.

Miller, S.M., Shoda, Y., & Hurley, K. (1996) Applying cognitive-social theory to health-protective behavior: Breast self-examination in cancer screening. Psychological Bulletin, 119: 70-94.

Appendices: NONE

Supporting Data: NONE